

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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PURDUE PHARMA PRODUCTS L.P.,  
NAPP PHARMACEUTICAL GROUP LTD.,  
BIOVAIL LABORATORIES INTERNATIONAL,  
SRL, and ORTHO-MCNEIL, INC.,

Plaintiffs/Counterclaim-defendants,

v.

PAR PHARMACEUTICAL, INC. and  
PAR PHARMACEUTICAL COMPANIES, INC.,

Defendants/Counterclaim-plaintiffs.

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Civil Action No. 07-255-JJF  
Civil Action No. 07-414-JJF  
Civil Action No. 07-666-JJF  
(CONSOLIDATED)

**PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION  
TO COMPEL PRODUCTION OF FOREIGN DOCUMENTS**

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Plaintiffs Purdue Pharma Products L.P. (“Purdue”) and Napp Pharmaceutical Group Ltd. (“Napp”) hereby oppose defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.’s (collectively “Par”) Motion To Compel Production Of Foreign Documents.

**I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS**

On September 6, 2007, the parties and the Court participated in a Rule 16 status and scheduling conference. Both parties have served document requests and interrogatories. In response to Par’s discovery requests, the Purdue/Napp plaintiffs<sup>1</sup> have produced over 1.6 million pages of documents. Depositions are on-going.

On October 10, 2007, the Court entered a Scheduling Order. Under that Order, the fact discovery cut-off date is May 15, 2008 (D.I. 23).

Purdue and Napp served the objections to the discovery requests at issue on this motion on September 19, 2007 (D.I. 18). On March 25, 2008, defendants filed this motion to compel (D.I. 70).

**II. SUMMARY OF ARGUMENT**

**There has already been substantial production of the documents sought by this motion:** Par concedes that the nearly 1.6 million pages of documents produced by Purdue and Napp contain substantial information about the prosecution of Purdue’s foreign counterpart patent applications, and about the inter partes opposition proceedings and litigations relating to

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<sup>1</sup> Purdue and Napp are associated companies. Purdue is headquartered in the United States; Napp in England. A third associated company, Mundipharma, GmbH, is headquartered in Germany. The patents in suit, which are now owned by Purdue and Napp, were prosecuted by Euro-Celtique S.A., a Luxembourg corporation in whose name both companies prosecute patents around the world. For ease of reference in this brief, Purdue and Napp will refer to the prosecutions as if they were conducted by Purdue and/or Napp, rather than by Euro-Celtique.

those applications (Par Br. 14). Indeed, the documents that Par cites in support of its motion to compel are documents already produced by Purdue, by its outside U.S. patent prosecution counsel, Davidson, Davidson & Kappel (“DDK”), by Napp, and by Mundipharma GmbH (“Mundipharma”), a German company affiliated with Purdue and Napp (Colletti Exs. D, E, G-J). There appears to be no dispute that:

- Purdue/Napp have produced all non-privileged documents relating to counterpart foreign patent proceedings to the extent that information was in the possession of DDK.
- Purdue/Napp have produced/scheduled documents relating to foreign proceedings concerning the four foreign applications that are cited in the ‘887 patent as “priority documents,” *i.e.*, the applications that form the basis for the U.S. application itself (Par Br. 14).

**Identification of already-produced documents:** In response to Par’s requests before this motion, Purdue/Napp provided an identification of those foreign documents from the DDK document production (Colletti Ex. C). At the time, Purdue/Napp did not have the means to perform a similar search on their own document production. A partially searchable database has since been created. With this opposition, Purdue/Napp are identifying to Par produced documents responsive to the requests at issue, *infra*, p. 5. Other documents have been withheld on the grounds of privilege and are being scheduled.

**Par’s motion should be denied:** Pursuant to Rule 26(b)(2)(C)(i), Fed. R. Civ. P., the Court should limit discovery where, as here, Par can obtain the information that it seeks “from some other source that is more convenient, less burdensome, or less expensive” than seeking it from Purdue/Napp. The documents that Par seeks on this motion are *publicly*

available files from various international patent offices. Par has made no showing that it has tried to obtain the public foreign documents from another source. The documents may be available through a patent search firm or even available on the Internet. At most, to obtain publicly available foreign files, Par need only contact patent agents in those foreign countries to have the documents copied from public files.

In contrast, the burden to Purdue of collecting and producing these papers is, without a doubt, substantial. Purdue/Napp would need to review its own files and the files of its patent counsel in each of forty countries concerning foreign patent applications that are not listed on the patents in suit, as well as any foreign oppositions or litigations. Those files would then need to be separated into privileged and non-privileged documents. The documents withheld on the grounds of privilege would then need to be scheduled. Purdue already did this for its U.S. prosecution counsel's files, and it was a substantial undertaking. There is no sound reason to subject Purdue/Napp to the burden of conducting what Par itself concedes is a fishing expedition (Par Br. 12; *infra* p. 12).

A total of eighty-five foreign patent applications were filed in forty different countries. Each was prosecuted under the procedural and substantive patent law of that country. Absent some showing of the relevance of foreign law and the foreign claims that were prosecuted to U.S. patent law and the claims prosecuted in the U.S., Par has not established that statements made to any foreign patent office are relevant to any claim or defense in this action. Under Rule 26(b)(2)(C)(iii), Fed. R. Civ. P., the Court can deny discovery of information of marginal relevance, if any, to the issues that will come before the Court.

Par has known of Purdue/Napp's objection to providing this information since September 2007, when Purdue and Napp objected to the requests now at issue. Par waited over

six months to bring this motion, instead of simply getting the public information it says it needs from public sources. There is no reason to further multiply the cost and complexity of fact discovery a month before fact discovery will end pursuant to the Scheduling Order in this action.

### **III. STATEMENT OF FACTS**

#### **A. To the extent the foreign patent documents appeared in the files of Purdue's U.S. patent counsel, those documents have been produced to Par**

In response to Par's discovery requests, Purdue and Napp have produced over 1.6 million pages of documents. This includes over a million pages from Purdue; over 350,000 pages from Napp; over 240,000 pages from Mundipharma (an associated company of Purdue in Germany); and about 24,000 pages from Davidson, Davidson & Kappel ("DDK"), the U.S. law firm that prosecuted the applications for the two patents now in suit (De Dec. ¶ 3).<sup>2</sup>

During prosecution of the U.S. patents in suit, the applicants and their attorneys submitted to the PTO the papers that were filed and art that was cited in various foreign proceedings. These include the oppositions in foreign patent offices to counterpart applications to the patents in suit and foreign litigations. In fact, Purdue submitted the art and argument made by both sides (*see, e.g.*, De Ex. 1). For example, DDK's production to Par included papers filed in the *Temmler* litigation, for which Par claims it needs additional discovery (*see, e.g.*, De Exs. 2-3). Yet Par admits it is already aware of the outcome of that litigation (Par Br. 13), presumably from what Purdue/Napp have produced or from a public source.

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<sup>2</sup> De Dec. ¶ \_\_ and De Ex. \_\_ refer to the corresponding paragraphs and exhibits to the April 11, 2008 Declaration of Sona De In Support Of Plaintiff's Opposition To Motion To Compel Production Of Foreign Documents.

**B. Purdue/Napp's production of the four "priority" applications, and other foreign patent documents**

Par complains that Purdue has "refused" to identify the production numbers corresponding to the foreign prosecution files that have already been produced, *i.e.*, the files relating to the four priority applications (one German, three British) upon which the U.S. application at issue was based (Par Br. 2). This is not correct.

In response to Par's request, Purdue identified ranges of production numbers in which over 6,000 pages of foreign prosecution documents can be found, from the DDK production (*see* Colletti Exhibit C). Par itself has located additional copies of these documents in Purdue's production (*see* Colletti Exhibit D).

When Par made its previous requests, Purdue/Napp had not completed processing the documents produced from Napp and Mundipharma into a searchable data base. Because the Court ordered document production to proceed on a somewhat expedited basis, Purdue/Napp focused their initial efforts on reviewing the documents, attempting to separate privileged documents from non-privileged ones, and producing them to Par. This process was substantially complete by January 4, 2008, as ordered. After production was complete, Purdue began the process of "coding" the produced documents so that they could be searchable to some extent (De Dec. ¶ 4).

Purdue can now search for and identify additional documents in the production that relate to the four foreign priority applications that form the basis of the U.S. application. A list of those production pages is provided in De Dec. ¶ 5.

Moreover, to the extent documents related to other foreign patent proceedings were kept with or attached to documents produced from Purdue/Napp's files, they too were either produced or scheduled on a privilege log as the case may be. As such, Purdue/Napp



maintained the integrity of the produced files notwithstanding that some of the foreign patent proceeding documents therein are not relevant to the patents in suit. Par's own motion shows that Purdue/Napp produced such documents (*see, e.g.*, Colletti Exs. H-J re: foreign oppositions).

**C. Purdue's objections to Par's discovery requests have been consistent and sound**

Par correctly quotes from the ten document requests it has served demanding production, without limitation, of all documents relating to any foreign prosecution or inter partes patent office proceedings relating to controlled release tramadol, but omits Purdue/Napp's objections to those requests (Par Br. 7-8). Par suggests that Purdue's position with respect to Par's document requests has somehow changed over time (Par Br. 2). This is simply incorrect. Purdue has always objected to Par's requests on the grounds that they were overly broad and that the marginal relevance, if any, of the discovery sought was far outweighed by the burden to Purdue of reviewing and processing these documents. For example, Par's request number 13 sought "[a]ll documents concerning any foreign counterpart application (including but not limited to an international or PCT application) of any U.S. patent application for the patent-in-suit." Purdue's September 19, 2007 response stated:

Purdue objects to this request as overly broad and unduly burdensome.

Purdue objects to this request to the extent that it seeks the production of documents and things not in the possession, custody, or control of Purdue.

Purdue objects to this request to the extent that it seeks publicly available documents.

Purdue objects to this request to the extent it seeks production of documents subject to the attorney-client privilege, the work product immunity, or both.

Subject to Purdue's General Objections and the foregoing specific objections, Purdue will produce relevant, non-privileged, non-immune documents responsive to this request.

(De Ex. 4, p. 10). Napp's response was to the same effect (De Ex. 5). Subject to the objections, as discussed above, Purdue produced those foreign prosecution materials that relate to the U.S. prosecution of the patents in suit.

**D. The burden to Purdue of producing these documents would be great**

Purdue has filed a total of eighty-five counterpart applications in forty countries.<sup>3</sup> Purdue has numerous counsel representing it across the world (De Dec. ¶ 6). Par argues, without support, that these documents "should be centrally located in plaintiffs' files" (Par Br. 15). This is incorrect. There are files relating to these applications within the legal department at Napp (De Dec. ¶ 8). But Par's requests also seek the files kept by Purdue's foreign outside counsel across the world.

More importantly, the patent files kept at Napp contain both public and privileged materials. The privileged material includes, for example, confidential correspondence between Napp and its outside counsel discussing the foreign proceedings and correspondence reflecting both Napp's and the law firms' considerations of how to proceed at various stages of those

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<sup>3</sup> As used in this brief, a "counterpart application" means an application that claims priority to the four applications (DE 4315525, GB 9324045, GB 9404544, and GB 9404928) to which the U.S. patent in suit (6,254,887) claims priority. This is not a representation that any counterpart application contains the same claims or disclosure as that of the patents in suit. As of last spring and summer, when Purdue began collecting documents for production, counterpart applications were filed in Argentina, Austria, Australia, Belgium, Bulgaria, Canada, Switzerland, Chile, China, Czech Republic, Germany, Denmark, Egypt, Spain, Finland, France, United Kingdom, Greece, Hungary, Indonesia, Republic of Ireland, Israel, India, Italy, Japan, Republic of Korea, Luxembourg, Mexico, Netherlands, Norway, New Zealand, Philippines, Pakistan, Poland, Portugal, Sweden, Singapore, Slovakia, Thailand, and Taiwan (De Dec. ¶ 7 (on information and belief)).

proceedings (De Dec. ¶ 9). Files of foreign outside counsel would likely have the same type of privileged communications.

Thus, even if there were only one file for each foreign counterpart application, reviewing those files for production would require Purdue/Napp to: (1) collect files from both Napp and its various local foreign counsel; (2) review both sets of files for privileged and non-privileged materials; (3) process the public documents for production; and (4) prepare a schedule of materials withheld subject to claims of privilege or work product for the remaining documents.

This last step, segregating and scheduling withheld documents, is itself significant. In response to the subpoena to Purdue's U.S. prosecution firm, DDK, a total of 24,715 pages were produced. An additional 999 documents were withheld. The schedule for those withheld documents was 357 pages long (De Dec. ¶ 10).

#### **IV. ARGUMENT**

##### **A. Par's motion ignores Rule 26(b)(2), which requires the Court to weigh the relative burden to the parties of obtaining discovery**

Par's basis for seeking production of the public documents relating to Purdue's foreign patent prosecutions is the broad definition of "relevance" in Rule 26(b)(1), Fed. R. Civ. P. (Par. Br. 9). Purdue's objections, however, are based on the mandatory limitations on discovery that now appear in Rule 26(b)(2)(C). The rule states:

On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;

. . . or

(iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

The purpose of these limitations is to permit the Court to set limits to discovery where, as here, the party propounding the discovery has not shown that the discovery is relevant or where that relevance, if any, is marginal and outweighed by the burden to the party from whom discovery is sought.

*Novartis Pharmaceuticals Corp. v. Abbott Laboratories*, 203 F.R.D. 159 (D. Del. 2001), is directly on point. In that patent infringement action, the patentee had produced certain documents relating to "core" foreign regulatory proceedings. *Id.* at 164. The alleged infringer moved to compel production of all foreign regulatory files and related correspondence. The Court denied the motion to compel on the grounds that such production would be duplicative, cumulative, and burdensome for the patentee. *Id.*

In addition, discovery can and should be limited where the party seeking the discovery can obtain the information it seeks without burdening another party (*see infra* section C).

The case law relied on by Par is inapposite (Par Br. 10-11). Those cases deal with issues of admissibility at trial, not whether a motion to compel discovery should be granted in view of the limitations of Rule 26(b)(2)(C).<sup>4</sup> If anything, Par's cases support Purdue's position that the relevance of such foreign documents is limited at best, and turns on the specific issues

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<sup>4</sup> In *Tanabe Seiyaku Co. v. United States ITC*, 109 F.3d 726, 733 (Fed. Cir. 1997), the Federal Circuit refused to find estoppel with respect to U.S. claims based on representations before foreign patent offices. Similarly, in *Liposome Co. v. Vestar, Inc.*, No. 92-332, 1994 U.S. Dist. LEXIS 19325 (D. Del. Dec. 20, 1994), the Court refused to apply judicial estoppel based on representations by a patentee to a foreign patent office.

being argued and a comparison of foreign law to the comparable provisions of the U.S. patent statute.<sup>5</sup>

**B. Par's arguments of alleged relevance are unsupported and unsound**

Par argues that the materials are relevant to show “how those skilled in the art understand the claims of the [U.S.] ‘887 patent [in suit]” (Par Br. 1). Par offers no support for this argument, and there is none. The ‘887 patent was issued by the PTO, applying U.S. law to the claims prosecuted by the applicants and their U.S. counsel. The claims of *foreign* patents were prosecuted, or are being prosecuted, under the patent laws of at least forty different foreign countries.

Par has made no showing that the ‘887 or ‘430 patent claims -- the claims that were allowed in the United States -- were the subject of any foreign proceeding. Nor has Par shown how the standards for patentability in any of those countries (or the procedural law under which those patents are prosecuted) relate in any way to the patentability standards of U.S. law. Nor has Par shown how anyone -- Purdue or any foreign opponent -- has “understood” the U.S. claims in any foreign proceeding.

Par next argues that foreign patent prosecutions are relevant to show “the patentees’ understanding of the scope of the alleged invention prior to this litigation” (Par Br. 11). To the extent Par seeks documents relating to foreign *litigations* and other inter partes

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<sup>5</sup> The Federal Circuit has stated that “varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations *inappropriate*.” *Caterpillar Tractor Co. v. Berco, S.p.A.*, 714 F.2d 1110, 1116 (Fed. Cir. 1983) (emphasis supplied). This Court has recognized that foreign patent prosecutions “*may* be relevant in *certain* circumstances,” and that adjudications of patent rights in foreign jurisdictions may have “*limited* relevance.” In *Pfizer Inc. v. Ranbaxy Labs., Ltd.*, 2005 U.S. Dist. LEXIS 34901, at \*10-\*11 (D. Del. 2005), the Court admitted evidence of a decision from a foreign patent office as “not entirely irrelevant” but did not address the weight of the evidence.

foreign patent office proceedings (Par Br. 12-14), this argument is logically inconsistent and should be rejected for this reason alone. To the extent the *Temmler* litigation was brought to the attention of the PTO, papers from that litigation were produced to Par by Purdue's U.S. counsel, DDK (De Exs. 2-3).

Par argues that it is entitled to learn why corresponding patent applications were rejected in some foreign patent offices (Par Br. 4-5, 11). Purdue disagrees. The claims were prosecuted under foreign law, and may or may not have been of a similar scope to the claims sought and obtained by the inventors in the U.S. Par has made no showing why the decision of a foreign patent office with respect to claims of unknown scope applying unknown law and procedure is relevant to any claim or defense under U.S. law in this action.<sup>6</sup>

Par next argues that the applicants' statements to foreign patent offices "may" be a source of admissions with respect to the prior art (Par Br. 1, 7, 11). Again, without proof of the degree of correspondence, if any, between the claims at issue overseas and the claims at issue here, as well as the similarities and differences between U.S. law and foreign law, such "admissions" would be of little or no value to the Court. *See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072 n.2 (Fed. Cir. 1994) (Withdrawal of a European patent application was not an admission of unpatentability, but rather a business decision made by a company with patent applications pending in several other countries.

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<sup>6</sup> Par has inserted in its brief references to facts unrelated to this motion, *e.g.*, its newly-minted contentions of unenforceability (Par Br. 3 re: U.S. Patent No. 5,580,578). Par has not shown how any of these arguments bear on what is at issue on this motion: the issue of whether, to the extent Par wants further production of public documents from foreign patent proceedings, it can and should obtain those documents itself. Purdue/Napp will respond to Par's contentions of unenforceability at the appropriate time in this action. This motion to compel is not that time.

“Caution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved.”). And the mere possibility that such admissions may exist does not justify putting Purdue to the burden of reviewing and producing documents from prosecution files in forty foreign countries, plus the corresponding documents in Napp’s files.

The bottom line on relevance is that Par does not know what it is looking for; it just wants Purdue to collect the documents in the slim hope that something will turn up. Par admits as much on page 12 of its brief: “Moreover, it is currently unknown to Par what other information will be found in the prosecution histories of the corresponding foreign patent applications. Nevertheless, the requested documents are relevant and discoverable.” On the showing made by Par, they are neither relevant nor discoverable.

**C. It would be easier for Par to obtain the documents itself than to subject Purdue to the burden of reviewing scores of files for privileged and unprivileged materials**

Pursuant to Rule 26(b)(2)(C)(i), the Court must deny Par’s motion if “the discovery sought . . . can be obtained from some other source that is more convenient, less burdensome, or less expensive.” That is plainly the case here.

Par has not shown that it is unable to obtain the publicly available documents from any foreign proceeding. Presumably, Par could obtain such documents through a patent search firm, here or overseas, or through foreign patent agents. Some papers may even be available electronically.

Purdue/Napp face a far greater burden to comply with Par’s requests. First, Purdue/Napp would need to collect two sets of files, the files at Napp and the files in the possession of Napp’s various foreign counsel. Second, both sets of files would need to be

screened for privileged and non-privileged materials. Third, Purdue would have to process the documents for production. Fourth, Purdue would have to create a schedule of documents withheld for privilege. As detailed *supra* p. 8, this has proved to be a large undertaking just for the U.S. prosecution files produced by Purdue's U.S. counsel, DDK.

What Par asks is for Purdue to take the substantial work it has already done for the U.S. prosecution and multiply it by the forty countries in which Purdue has prosecuted foreign counterparts. The exercise could take months and cost hundreds of thousands of dollars (De Dec. ¶ 11). Discovery is set to close in this action on May 15 (D.I. 23). There is no practicable, inexpensive way to provide discovery of the breadth and scope that Par seeks by this motion.

Moreover, the cost and delay are Par's doing, not Purdue's. Par has known for six months that Purdue objected to providing this discovery, and the grounds for Purdue's objections, *supra* pp. 6-7. Par waited from September 19, 2007, when it first learned of Purdue's objections, until March 25, 2008, to bring this motion. If, instead, Par had simply set out to obtain then the papers that it says it wants now, Par would be done already. And it would be done without burdening the Court with this motion and seeking to burden Purdue with the cost of providing discovery whose relevance is marginal, if relevant at all.

**D. There should be no further dispute as to the identification of foreign patent prosecution documents already produced**

As discussed *supra* p. 5, Purdue has given Par additional information now available identifying documents relating to the prosecution of the four foreign applications upon which the Purdue patents in suit are based. This should resolve Par's motion to the extent it seeks additional identification of production page ranges relating to these foreign prosecutions (Par Br. 15).



**V. CONCLUSION**

For the reasons set forth above, Par's Motion To Compel Production Of Foreign Documents should be denied.

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 11, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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